



CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2021-0006]

Title: Notice of Availability: Proposed Guidance on Alternative Test Methods and Integrated Testing Approaches

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is announcing the availability of a document titled, “Proposed Guidance for Industry and Test Method Developers: CPSC Staff Evaluation of Alternative Test Methods and Integrated Testing Approaches and Data Generated from Such Methods to Support FHSA Labeling Requirements.” The Commission requests comments on the proposed guidance.

DATES: Submit comments by [Insert date 75 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2021-0006, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (e-mail), except through <https://www.regulations.gov>. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479; email: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number for this

notice. CPSC may post all comments received without change, including any personal identifiers, contact information, or other personal information provided, to:

<https://www.regulations.gov>. Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC-2021-0006, into the “Search” box, and follow the prompts. The proposed guidance is available under “Supporting and Related Material.” It is also available on the Commission’s website at: <https://cpsc.gov/s3fs-public/NOA-Proposed-Guidance-on-Alternative-Test-Methods-and-Integrated-Testing-Approaches.pdf?NDYVpNRIAMpOPJDPzlt770dvxnvPJHh6> and from the Commission’s Division of the Secretariat.

FOR FURTHER INFORMATION CONTACT: John Gordon, Toxicologist, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2025; email: jgordon@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1275, requires that hazardous substances bear certain cautionary statements on their labels. Manufacturers may perform toxicological tests to determine whether such products require cautionary labeling addressing the hazard. Although animals are still used in toxicological testing, most governmental agencies support reduced use of animals in testing, by promoting the acceptance of data from alternative test methods.

In 1997, the National Institute of Environmental Health Sciences (NIEHS), the National Toxicology Program (NTP), and 13 federal agencies (including CPSC) joined to form the

Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM). ICCVAM sponsors scientific review of non-animal tests (known as New Approach Methodologies or NAMs) that may reduce, refine, or replace animal tests in evaluating potential hazards. Reviews from ICCVAM and other federal agencies can provide a basis for regulatory agencies, such as CPSC, to consider non-animal testing alternatives for use in regulatory decision making. In the past, CPSC staff relied upon ICCVAM's validation of new alternative testing methods, as reliable test methods to determine compliance with the labeling requirements of the FHSA. However, ICCVAM no longer formally validates test methods.

In 2012, CPSC issued a policy on non-animal or alternative testing methods to support labeling requirements under the FHSA, as codified under 16 CFR 1500.232 (Animal Testing Policy). CPSC's website lists current CPSC-accepted alternative test methods and their conditions of use.¹ Since 2012, new advancements in toxicological testing, and, in particular, with NAMs, have occurred. NAMs include *in vitro* (in test tube), *in chemico* (all chemical test, no biological material), or *in silico* (computer models) methods and approaches used to test for toxicological effects in place of animal testing. In some cases, NAMs are combined with other NAMs or existing *in vivo* (animal) data to form an "integrated approach to testing and assessment" (IATAs).

The Commission reaffirms its policy to find alternatives to traditional animal testing that replace animals, reduce the number of animals tested, and decrease the pain and suffering in animals associated with testing household products. As such, the Commission strongly encourages all agency stakeholders to submit for evaluation by CPSC staff any scientifically validated alternative test methods that do not require animal testing for determining compliance with the labeling requirements under the FHSA.

Because ICCVAM no longer formally validates test methods, to assist stakeholders,

¹ <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Recommended-Procedures-Regarding-the-CPSCs-Policy-on-Animal-Testing/>

including the public, manufacturers, test method developers, and test laboratories, in determining what test methods are deemed reliable for determining compliance with the labeling requirements under the FHSA, CPSC staff drafted proposed guidance clarifying staff's informational requirements and process for evaluating NAMs and IATAs. As described in the proposed guidance, the types of information CPSC staff would use to evaluate NAMs or IATAs submitted to CPSC would include (but not be limited to): concordance and reproducibility data; false positive and false negative rates; applicability domain; test endpoint; validation studies; or any other pertinent information needed to make a determination. The proposed guidance also includes an optional NAM nomination form, which can be used to organize information about a NAM or IATA for CPSC staff evaluation. Such non-animal alternative test methods, if accepted by CPSC, would be considered reliable test methods for determining compliance with the labeling requirements under the FHSA. Additionally, CPSC would continue to list CPSC-accepted alternative test methods on CPSC's website.

The proposed guidance is not a rule and does not establish legal requirements. The proposed guidance is intended to inform stakeholders about what information CPSC staff uses to evaluate NAMs or IATAs for FHSA labeling determinations. The proposed guidance also informs stakeholders of CPSC staff's process for evaluating that information. Depending on the complexity of specific NAMs or IATAs, the information discussed in the guidance may or may not apply; and in some instances, staff may need additional information not specifically described in the guidance document to make an evaluation. The proposed guidance is available at: <https://www.regulations.gov> under docket number, CPSC-2021-0006, under "Supporting and Related Material", on the Commission's website at: <https://cpsc.gov/s3fs-public/NOA-Proposed-Guidance-on-Alternative-Test-Methods-and-Integrated-Testing-Approaches.pdf?NDYVpNRIAMpOPJDPzlt770dvxnvPJHh6>, and from the CPSC's Division of the Secretariat, as provided in the **ADDRESSES** section of this notice.

B. Request for Comments

The Commission invites comments on the “Proposed Guidance for Industry and Test Method Developers: CPSC Staff Evaluation of Alternative Test Methods and Integrated Testing Approaches and Data Generated from Such Methods to Support FHSA Labeling Requirements.” The CPSC will consider all timely comments before finalizing the guidance. Comments should be submitted by **[Insert date 75 days after date of publication in the Federal Register]**. Information on how to submit comments can be found in the **ADDRESSES** section of this notice.

Alberta E. Mills,
Secretary,
Consumer Product Safety Commission.
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